

REMARKS

Claims 77-86 and 109-148 are pending in the current application. Applicants have amended claims 119 and 137.

§§ 102/103

The Office Action rejected claims 77, 80-83, 109, 112-115, 119, 122-125, 128, 130-134, 137-139, and 142-146, including independent claims 77, 109, 119, 128, and 137 based on Bylsma, U.S. Patent No. 6,319,220 (“Bylsma”). The Office Action rejected all other pending dependent claims based on Bylsma in view of certain knowledge in the art, namely the timing sequences recited of 100 ms, 8 ms, and 25 ms.

Bylsma discloses a general phacoemulsification apparatus “configured for random pulse mode operation.” (Abstract) While not abundantly explained or differentiated in much detail within Bylsma, the Bylsma “random pulse mode operation” relates not to aspiration using pressure pulses, but to the application of ultrasonic energy during the phacoemulsification procedure. The opening paragraphs of Bylsma generally explain the difference between ultrasonic pulse delivery and fluid flow/aspiration:

...The conventional phacoemulsification apparatus includes a hand piece having an ultrasonic transducer for driving a hollow phacoemulsification needle. The hand piece is provided with an irrigation line and an aspiration line, and is configured for directing the flow of irrigation fluid through the needle into the eye. The hand piece is also provided with a sleeve surrounding the phacoemulsification needle, and is further configured for aspirating fluid to flow from the eye into a lumen defined between the needle and sleeve.

...

The conventional phacoemulsification apparatus includes a source for irrigation fluid (e.g. one or more bottles of irrigation

fluid) and a source of vacuum (e.g. peristaltic pump, venturi, vacuum pump, etc., or combinations thereof). The conventional phacoemulsification apparatus also includes a power supply and control for driving the ultrasonic hand piece, and thus the tip of the phacoemulsification needle. Typically, the conventional phacoemulsification apparatus includes a console containing the power supply, control (e.g. analog and/or microprocessor), peristaltic pump, and other components. The hand piece is electrically connected to the hand piece by a cable, and fluidly connected to the irrigation fluid supply and vacuum source by a tubing set.

Bylsma, Col. 1, ll. 12-59 (emphasis added)

The pulse mode is explained as ultrasonic energy pulses at for example, Col. 2, ll. 4-17 (emphasis added):

To minimize the “pushing” or repulsive effect of ultrasound waves propagating from the tip of the phacoemulsification needle on the nuclear fragments, the “pulse-mode” was created to energize the ultrasonic hand piece, and thus tip of the phacoemulsification tip intermittently. Accordingly, the repulsive force effect is only applied intermittently, allowing the aspiration (flow) rate to keep the free nuclear fragment(s) closer to the ultrasound tip for quicker removal. However, repulsion of a nuclear fragment is still frequently noted even with operation of the pulse-mode, especially when the pulse-rate is high. Low pulse-rates have been used to enhance prevention of occlusions with some success, but the prevention of enhanced occlusions is counterproductive to certain techniques of phacoemulsification.

Throughout the Bylsma reference, use of the phrases “pulse mode,” “random pulse mode” and so forth **always** refer to ultrasonic pulses, not aspiration pulsing or aspiration negative pressure pulse application or other fluid operation. Thus the Bylsma reference materially differs from what is presently claimed.

The Office Action cites aspirating by aspiration line 4 and correlates a “fluid control device” with Bylsma’s console 10. Office Action, p. 2. Aspirating fluid from an ocular region is said to be shown at col. 2, ll. 30-70 and col. 3, ll. 1-30. *Id.* Again, Applicants do not dispute that the Bylsma system aspirates fluid. However, Applicants strongly disagree that aspiration is performed using, for example, “modulated differential pressure pulses” as claimed in, for example, claim 77. The Office Action cites FIGs 7-9 and col. 5, ll. 25-50 to show “negative aspiration pulses or differing from the aspiration pulses...or having brief pauses between pulses.” This is simply not the claim language. FIGs. 7-9 illustrate ultrasound energy application, and the col. 5 passage simply describes aspiration in general, which differs from the present claim language, requiring “modulated differential pressure pulses” (claim 77).

Claim 77

Regarding individual independent claims, claim 77 requires:

aspirating the ocular region by applying a series of modulated differential pressure pulses to the ocular region via a fluid control device.

The claims specifically calls out “aspirating,” and thus any rejection based on passages discussing ultrasonic pulsing or pulse modes is inapposite. Also, the word “modulate” or “modulated” is employed throughout the present specification, and Webster’s Ninth New Collegiate Dictionary provides a definition of “modulate” as “to adjust to or keep in proper measure or proportion.” “Modulate” is therefore synonymous with “temper” or “regulate.” The word “differential” is self-explanatory, generally meaning exhibiting a difference. The concept of “aspirating...by applying a series of modulated differential pressure pulses” is not shown in Bylsma. Bylsma discusses

aspiration generally, without use of “modulated differential pressure pulses,” and therefore does not anticipate claim 77.

Claim 109

Claim 109 includes the limitation of “applying a series of modulated differential pressure pulses to the ocular region via a fluid control device.” As with claim 77, modulated differential pressure pulses are not shown by Bylsma – only “random pulse mode” operation and aspiration in a general sense. Thus claim 109 is not anticipated by Bylsma.

Claim 119

Claim 119 has been amended and recites:

applying modulated differential fluid pressure pulses to the ocular region; and

delivering modulated ultrasonic energy to the ocular region simultaneous with said applying.

This differentiates application of ultrasonic energy from applying modulated differential fluid pressure pulses to the ocular region. As noted, Bylsma does not do this, and thus Bylsma does not anticipate claim 119, as amended.

Claim 128

Claim 128 requires:

applying modulated differential pressure pulses to the ocular region to aspirate the ocular region; and

delivering modulated ultrasonic energy to the ocular region simultaneous with said applying.

Again, ultrasonic energy delivery is differentiated from application of modulated differential pressure pulses to aspirate the ocular region. This is not shown by Bylsma, which as noted addresses ultrasonic energy “random pulse mode” operation together with a generally standard aspiration arrangement. Thus claim 128 is not anticipated by Bylsma.

Claim 137

Claim 137, as amended, recites “applying a series of modulated differential fluid pressure pulses to an ocular region during the phacoemulsification procedure,” and as with the foregoing claims, such a “modulated differential fluid pressure [pulse]” application is not present in Bylsma. Thus Claim 137 is not anticipated by Bylsma.

103 Rejections

Applicants further note that with all dependent claims rejected under §103 based on Bylsma, namely claims 78-79, 84, 85-86, 110-111, 116-118, 120-121, 126-127, 129, 135-136, 140-141, and 147-148, and 20-24, the Office Action rejects the claims by combining Bylsma with purported knowledge in the art. For example, the Office Action states that “it would have been obvious...to use the duration values as claimed by Applicant since Bylsma discloses the duration and pulse amounts can be varied...” Office Action, p. 4.

Aside from the fact that Bylsma is discussing ultrasound energy application and not aspiration or fluid operation, in rejecting the claims, the Office Action relies on “general knowledge” or “personal knowledge” of the Examiner. In accordance with 37 C.F.R. § 1.104 (d)(2) and to preserve Applicants’ argument on appeal, **Applicants request that the Examiner provide an affidavit that supports the rejection of the claims based on the official notice, common knowledge, or personal knowledge of the Examiner, or provide a reference demonstrating the purported common knowledge.** See *In re Lee*, 277 F.3d 1338, 1344-45, 61 U.S.P.Q.2d 1430, 1435 (Fed. Cir. 2002) (finding that reliance on “common knowledge and common sense” did not fulfill

the PTO's obligation to cite references to support its conclusions, as PTO must document its reasoning's on the record to allow accountability and effective appellate review); *see also, In re Zurko*, 59 USPQ2d 1693 (Fed. Cir. 2001) ("This assessment of basic knowledge and common sense was not based on any evidence in the record and, therefore, lacks substantial evidence support. ... With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience -- or on its assessment of what would be basic knowledge or common sense"); Manual of Patent Examining Procedure 2144.03 ("If the applicant traverses [] an assertion [that a concept is 'well known' or 'matters of common knowledge'] the examiner should cite a reference in support of his or her position."). Should the Examiner continue to take issue with claim 34, or any other claims on this basis, Applicants request that the Examiner produce a reference showing "receiving light energy reflected from the specimen at a pixel" or otherwise in accordance with the express terminology of the claim or claims, or an affidavit in support of the rejection.

Applicants also note that broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence" of a motivation to combine the references. *In re Zurko*, 59 USPQ2d 1693 (Fed. Cir. 2001); *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact.")

Applicants further contend that there is no reasoning supporting combining Bylsma with the purported knowledge in the art, and that it is only through the use of impermissible hindsight that the Applicant's claims may be constructed from the reference and purported knowledge in the art. Such hindsight reconstruction of the invention is impermissible. *In Re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In Re Laskowski*, 871 F.2d 115, 117 (Fed. Cir. 1989); *see also, Ex Parte Lange*, 72 U.S.P.Q. 90, 91 (C.C.P.A. 1947).

For the foregoing reasons, Applicants respectfully submit that independent claims 77, 109, 119, 128, and 137, including those amended, are allowable over the reference cited. Further, all claims dependent from these allowable independent claims are allowable as they include limitations not shown in the cited reference, either alone or in combination with alleged general knowledge in the art.

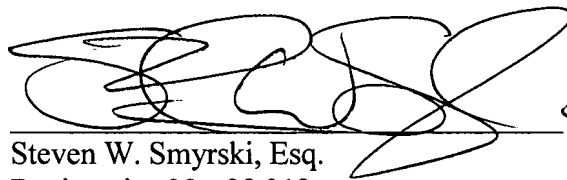
CONCLUSION

In view of the foregoing, it is respectfully submitted that all claims of the present application are in condition for allowance. Reexamination and reconsideration of all of the claims, as amended, are respectfully requested and allowance of all the claims at an early date is solicited.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Applicants believe that no fees are due in accordance with this Response. Should any fees be due, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment to Deposit Account 502026.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Smyrski', written over a horizontal line.

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